

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

200 (use as many sheets as necessary)

1 of 4

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|-------------------------------|--------------------|
| Application Number | 10/594,373 |
| Filing Date | September 27, 2006 |
| First Named Inventor | Alan Meehan |
| Group Art Unit | -- |
| Examiner Name | -- |
| Attorney Docket Number | 21438P |

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner
Signature

/Umamaheswari Ramachandran/

Date Considered

12/10/2009

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| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | COMPLETE IF KNOWN | | |
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| NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------|----------|---|
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| /U.R./ | AA | Roehrborn et al., Urology, Vol. 62 (2003), pp. 894-899, "Effects of finasteride on serum testosterone and body mass index in men with benign prostatic hyperplasia" |
| | AB | McConnell et al., J. Clin. Endocrinol. Metab., Vol. 74 (1992), pp. 505-508, "Finasteride, an inhibitor of 5 α -reductase, suppresses prostatic dihydrotestosterone in men with benign prostatic hyperplasia" |
| | AC | Page et al., J. Clin. Endocrinol. Metab., Vol. 90 (2005), pp. 1502-1510, "Exogenous testosterone (T) alone or with finasteride increases physical performance, grip strength, and lean body mass in older men with low serum T" |
| | AD | Amory et al., J. Clin. Endocrinol. Metab., Vol. 89 (2004), pp. 503-510, "Exogenous testosterone or testosterone with finasteride increases bone mineral density in older men with low serum testosterone" |
| | AE | Gormley et al., N. Eng. J. Med., Vol. 327 (1992), pp. 1185-1191, "The effect of finasteride in men with benign prostatic hyperplasia" |
| | AF | Marin et al., Obesity Research, Vol. 1 (1993), pp. 245-251, "Androgen treatment of abdominally obese men" |
| | AG | Boyanov et al., The Aging Male, Vol. 6 (2003), pp. 1-7, "Testosterone supplementation in men with type 2 diabetes, visceral obesity and partial androgen deficiency" |
| | AH | Rebuffe-Scrive et al., Int'l J. of Obesity, Vol. 15 (1991), p. 791-795, "Short Communication: Effect of testosterone on abdominal adipose tissue in men" |
| | AI | Ford et al., JAMA, Vol. 287 (2002), pp. 356-359, "Prevalence of the metabolic syndrome among U.S. adults" |
| | AJ | Parsons et al., Cancer Epidemiol. Biomarkers Prev., Vol. 14 (2005), pp. 2257-2260, "Serum testosterone and the risk of prostate cancer ..." |
| | AK | Thompson et al., N. Eng. J. Med., Vol. 349 (2003), pp. 215-224, "The influence of finasteride on the development of prostate cancer" |
| | AL | Laaksonen et al., Diabetes Care, Vol. 27 (2004), pp. 1036-1041, "Testosterone and sex hormone-binding globulin predict the metabolic syndrome and diabetes in middle-aged men" |
| | AM | Laaksonen et al., Eur. J. of Endocrinol., Vol. 149 (2003), pp. 601-608, "Sex hormones, inflammation and the metabolic syndrome: a population-based study" |
| | AN | Keating et al., J. of Clin. Oncology, Vol. 24 (2006), pp. 4448-4456, "Diabetes and cardiovascular disease during androgen deprivation therapy for prostate cancer" |
| ↓ | AO | Dhindsa et al., J. of Clin. Endocrinol. Metab., Vol. 89 (2004), pp. 5462-5468, "Frequent occurrence of hypogonadotropic hypogonadism in type 2 diabetes" |

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| /U.R./ | AP | Shores et al., Arch. Intern. Med., Vol. 166 (2006), pp. 1660-1665, "Low serum testosterone and mortality in male veterans" |
| | AQ | Kaplan et al., J. of Urology, Vol. 176 (2006), pp. 1524-1528, "The age related decrease in testosterone is significantly exacerbated in obese men with the metabolic syndrome ..." |
| | AR | Pitteloud et al., Diabetes Care, Vol. 28 (2005), pp. 1636-1642, "Relationship between testosterone levels, insulin sensitivity, and mitochondrial function in men" |
| | AS | Belanger et al., Horm. Metab. Res., Vol. 34 (2002), pp., 737-745, "Adipose tissue intracrinology: Potential importance of local androgen/estrogen metabolism in the regulation of adiposity" |
| | AT | Liverman et al. (editors), Testosterone and Aging (2002), Institute of Medicine of the National Academies, The National Academies Press, Washington, DC, pp. 1-211 |
| | AU | Marks et al., JAMA, Vol. 296 (2006), pp 2351-2361, "Effect of testosterone replacement therapy on prostate tissue in men with late-onset hypogonadism" |
| | AV | Uygur et al., Steroids, Vol. 63 (1998), pp. 208-213, "Effects of the 5alpha-reductase inhibitor finasteride on serum levels on gonadal, adrenal, and hypophyseal hormones and its clinical significance ..." |
| | AW | Bialek et al., Pol. J. Pharmacol., Vol. 56 (2004), pp. 509-518, "Neuroprotective role of testosterone in the nervous system" |
| | AX | Okun et al., Neurology, Vol. 62 (2004), pp. 411-413, "Plasma testosterone levels in Alzheimer and Parkinson diseases" |
| | AY | Tan et al., The Aging Male, Vol. 6 (2003), pp. 13-17, "A pilot study on the effects of testosterone in hypogonadal aging male patients with Alzheimer's disease" |
| | AZ | Moffat et al., Neurology, Vol. 62 (2004), pp. 188-193, "Free testosterone and risk for Alzheimer disease in older men" |
| | BA | Okun et al., Arch. Neurol., Vol. 59 (2002), pp. 1750-1753, "Beneficial effects of testosterone replacement for the nonmotor symptoms of Parkinson disease" |
| | BB | Roehrborn C, Andriole A, Nickel JC, Boyle P, Hofner K. Effect of the dual 5alpha-reductase inhibitor dutasteride on endocrine parameters and prostate volume. European Urology, Vol. 41 (2002), (1 Suppl. 1), 107. Poster included. |
| | BC | Rhoden et al., N. Eng. J. Med., Vol. 350 (2004) pp. 482-492, "Risks of testosterone-replacement therapy and recommendations for monitoring" |
| | BD | Kastelstein et al., Am. J. of Cardiology, Vol. 86 (2000), pp. 221-223, "Comparison of effects of Simvastatin versus Atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-1 Levels" |

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/U.R./

BE

Crouse et al., Am. J. Cardiology, Vol. 83 (1999), pp. 1476-1477, "Effects of high doses of Simvastatin and Atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-1"

BF

Westerbacka et al., J. Clin. Endocrinol. Metab., Vol. 88 (2003), pp. 4924-4931, "Body fat distribution and cortisol metabolism in healthy men: Enhanced 5 β -reductase and lower cortisol/cortisone metabolite ratios ..."

BG

Andrew et al., J. Clin. Endocrinol. Metab., Vol. 83 (1998), pp. 1806-1809, "Obesity and gender influence cortisol secretion and metabolism in man"

BH

Amory et al., J. Clin. Endocrinol. Metab., Vol. 90 (2005), pp. 2610-2617, "Oral testosterone in oil plus dutasteride in men: A pharmacokinetic study"

BI

Leibowitz et al., Am. Society of Clinical Oncology, Abstract 1617 (2003), "Primary hormonal therapy with finasteride and bicalutamide in advance prostate cancer (CaP)"

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